REMARKS

Claim 18 has been amended to delete the language "wherein the scores are generated during nucleic acid amplification and wherein the scores are used, during nucleic acid amplification, to ascertain whether the nucleic acid is present in the sample" and to add the language "to process the scores during amplification." Support for this claim amendment can be found on page 2, lines 14-15 of the specification.

Applicants acknowledge that these amendments are being made after final rejection and that entry of amendments after final are at the Examiner's discretion. They were not presented earlier because it was believed that these amendments were not necessary to complete response to the last Official Action. Further the amendments are responsive to the Examiner's most recent rejections in the present Official Action, and they put the claims in condition for allowance or in better form for appeal, and they do not raise any new issues or require further search. Applicants respectfully request that the Examiner exercise her discretion in favor of entry of the amendments under these circumstances.

The Examiner has rejected claims 18-23 under 35 U.S.C. § 112, ¶ 1 for lack of a written description. The Examiner indicates that the claim amendment made in the response to the previous office action, to amend claim 18 to add the language "wherein the score is generated during amplification and wherein the score is used, during amplification, to ascertain whether the nucleic acid is present in the sample" constitutes new matter.

Applicants do not agree. There is support for this language in the specification. For example, on page 2, lines 14-15 of the application, in describing what the invention provides, it is stated in the specification that "initiation of the analysis algorithm can be implemented prior to completion of temperature cycling" and that "data processing can occur during amplification." Accordingly, in one embodiment, the scores can be generated and analyzed during amplification.

Although Applicants do not agree that the specification lacks written description support for claim 18, as previously amended, Applicants have deleted the language objected to by the Examiner. Applicants have amended claim 18 to contain the phrase "to process the scores during amplification." This language has written description support on page 2, lines 14-15 of the specification which state that "data processing can occur during amplification" and that "initiation of the analysis algorithm can be implemented prior to completion of temperature cycling." Withdrawal of the rejection of claims 18-23 under 35 U.S.C. § 112, ¶ 1 is respectfully requested.

The Examiner has also rejected claims 18-23 under 35 U.S.C. § 102(a) and 102(e) as being anticipated by Schork et al. (U.S. Patent No. 6,291,182; hereinafter the '182 patent). Applicants respectfully traverse the Examiner's rejection. The '182 patent does not anticipate claim 18, as amended, or its dependent claims 19-23.

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). Claim 18 of the above-captioned application specifies a processor that is programmed "to process data during amplification" to clarify that a characteristic of the claimed device is that the processor is programmed to analyze data during amplification of the nucleic acids. Again, as stated in the specification, "initiation of the analysis algorithm can be implemented prior to completion of temperature cycling" and "data processing can occur during amplification." The '182 patent does not describe a processor that analyzes data during amplification of nucleic acids to ascertain whether the nucleic acid is present in the sample.

The Examiner indicates that the '182 patent discloses a fluorimeter and Picogreen to determine quantities of amplification products and refers to column 47, lines 7-9 of the '182 patent (Example 6). However, although Example 6 discloses a fluorimeter and

the use of Picogreen to quantitate nucleic acids, the fluorimeter and Picogreen are used to determine quantities of amplification products after amplification is complete in samples from the amplification reaction after final elongation that are aliquoted into 96-well plates. Thus, the quantities of amplification products are determined after the amplification reaction is complete (see column 47, lines 1-9).

The Examiner also refers to the sequencing method described in Example 6 and indicates that the '182 patent discloses the use of dideoxy terminator sequencing reactions to determine sequences of amplification products wherein the sequence data is evaluated using software designed to detect sites among the amplified products via different fluorescent molecules and by evaluating intensity ratios. The Examiner refers to column 47, lines 10-15 and column 47, lines 10-28 in Example 6 of the '182 patent. However, the sequencing reactions described in Example 6 of the '182 patent are done using dideoxy terminators, each labeled with a different fluorescent molecule, and the sequences are analyzed by running the products of the sequencing reaction on sequencing gels and then using gel image analysis of the sequencing gels to determine the sequences (see column 47, lines 11-36). According to the Examiner, the "fluorescence measurement" in this sequencing protocol is the gel image analysis that is used to determine the sequence. The sequence data from the gel image analysis is then evaluated using software designed to detect the presence of a nucleic acid in a sample. Thus, the fluorescence measurement that is related to the sequencing protocol described in Example 6 is not done during amplification of the nucleic acid. Rather the gel image analysis (*i.e.*, the fluorescence measurement) is done on samples run on a sequencing gel and the samples are run on the sequencing gel after amplification is complete. A similar method is described in Example 17 and is also referred to by the Examiner.

The Examiner suggests that "amplification" may include amplified PCR products. However, claim 18 specifies that a characteristic of the processor is that the processor is programmed to process the scores "during amplification." It is very clear to a skilled artisan that the phrase "during amplification" does not include samples that have been aliquoted into a microtiter plate and are no longer undergoing thermal cycling (as described in Example 6 of the '182 patent) or samples that are being run on a sequencing gel and are not undergoing thermal cycling (as described in Examples 6 and 17 of the '182 patent).

Accordingly, for the devices and methods described in the '182 patent, the fluorescence measurements are done after the amplification of the nucleic acids is complete and the analysis of the data generated from the fluorescence measurements is done after amplification of the nucleic acids is complete. No where does the '182 patent describe a processor programmed to process data during amplification of nucleic acids. Thus, the '182 patent does not describe all of the required elements of claims 18-23 and the '182 patent cannot anticipate claims 18-23. Withdrawal of the rejection of claims 18-23 under 35 U.S.C. § 102(a) and 102(e) is respectfully requested.

CONCLUSION

The foregoing amendments and remarks are believed to fully respond to the Examiner's rejection. The amended claims are in condition for allowance. Applicants respectfully request allowance of the claims, and passage of the application to issuance.

Respectfully submitted,

Rebecca Ball

Rebecca L. Ball
Registration No. 46,535
Attorney for Applicant

(317) 231-7511
Indianapolis, Indiana 46204